

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis, 5(c) and 72.2)

To:

HASEGAWA, Yoshiko  
SOEI PATENT AND LAW FIRM, Ginza First Bldg., 10-6,  
Ginza 1-chome, Chuo-ku, Tokyo  
1040061  
JAPON

(No. 103)

Date of mailing (day/month/year)  
31 August 2005 (31.08.2005)

Applicant's or agent's file reference  
FP04-0339-00

**IMPORTANT NOTIFICATION**

International application No.  
PCT/JP2004/019223

International filing date (day/month/year)  
22 December 2004 (22.12.2004)

Applicant  
Eisai Co., Ltd. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

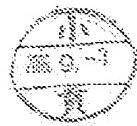
The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

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## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP04-0339-00	FOR FURTHER ACTION		See item 4 below
International application No. PCT/AU2004/019223	International filing date (day/month/year) 22 December 2004 (22.12.2004)	Priority date (day/month/year) 25 December 2003 (25.12.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant: Eisai Co., Ltd.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 22 August 2006 (22.08.2006)
Faxsimile No. +41 22 338 82 70	Authorized officer  Yoshiko Kuwahara e-mail: pi07@wipo.int

PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

TRANSLATION  
PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference <b>FP04-0339-00</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. <b>PCT/JP2004/019223</b>	International filing date (day/month/year) <b>22.12.2004</b>	Priority date (day/month/year) <b>25.12.2003</b>
International Patent Classification (IPC) or both national classification and IPC		
Applicant <b>Eisai Co., Ltd.</b>		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1(b)(v) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/019223

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- This opinion has been established on the basis of a translation from the original language into the following language:  
(which is the language of a translation furnished for the purposes of international search under Rule 12.3 and 23.1(b))
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material:  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material:  
 in written format  
 in computer readable form
  - c. time of filing/furnishing:  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/019223

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application

claim Nos. 49

because:

the said international application, or the said claims No(s). 49

relate to the following subject matter which does not require an international preliminary examination (specify):

Claim 49 relates to human body treatment techniques based on surgery or therapy.

the description, claims or drawings (indicate particular elements below) or said claims Nos. \_\_\_\_\_

are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. 49

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- has not been furnished  
 does not comply with the standard

the computer readable form

- has not been furnished  
 does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019223

Box No. V

Required statement under Rule 43bis (i) and (ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.

1. Statement

Novelty (N)	Claims _____	1-48, 50	YES
	Claims _____		NO
Inventive step (I)	Claims _____		YES
	Claims _____	1-48, 50	NO
Industrial applicability (IA)	Claims _____	1-48, 50	YES
	Claims _____		NO

2. Citations and explanations:

(Documents)

1. WO 2002/032872 A1 (Eisai Co., Ltd.), 25 April 2002

(Explanation)

Regarding claims 1-48 and 50

Although the inventions of claims 1-48 and 50 are not disclosed in the documents cited in the ISR and are novel, they do not appear to involve an inventive step over document 1 cited in the ISR.

Document 1 describes compounds comprising 4-(3-chloro-4-(cyclopropylaminocarbonyl)aminophenoxy)-7-methoxy-6-quinolinecarboxamide, or their pharmacologically acceptable salts or hydrates thereof as compounds exhibiting angiogenesis-inhibiting action and useful in the treatment of various cancers, cancer metastases, retinal neovascularization, inflammatory conditions such as rheumatoid arthritis, and atherosclerosis, and, furthermore, mentions that they can be refined by recrystallization from appropriate solvents and that suggested pharmacologically acceptable salts include addition salts of organic sulfonic acid, such as methanesulfonic acid salts, toluenesulfonic acid salts, etc., as well as addition salts of inorganic acids, such as chlorides, sulfates, hydrogen bromides, etc. (page 92, line 19 through page 93 line 4), and that white crystals of 4-(3-chloro-4-(cyclopropylaminocarbonyl)aminophenoxy)-7-methoxy-6-quinolinecarboxamide are obtained in a working example (Working Example 368).

In addition, since it is a common practice to try to improve the stability and other physical properties of compounds used as drugs by converting them to salt, solvate, or crystalline form, a person skilled in the art would obviously try to prepare crystals of various salts and solvates of 4-(3-chloro-4-(cyclopropylaminocarbonyl)aminophenoxy)-7-methoxy-6-quinolinecarboxamide described in document 1 using appropriate publicly known methods.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/019223

Box No. VI	Certain documents cited			
1. Certain published documents (Rule 43bis.1 and 70.1(m))				
Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)	
WO 2004/101526 A1 [EX]	25.11.2004	22.04.2004	22.04.2003	
WO 2004/080462 A1 [EX]	23.09.2004	10.03.2004	10.03.2003	
WO 2004/029782 A1 [EX]	13.05.2004	29.10.2003	29.10.2002	
2. Non-written disclosures (Rule 43bis.1 and 70.9)				
Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)		